

K041268

1/3

SEP 20 2004

X. 510(k) SUMMARY

1. SUBMITTER'S NAME
2. CONTACT PERSON AT ADRI
3. DATE THAT 510(k) SUMMARY WAS PREPARED
4. NAME OF THE MEDICAL DEVICE (Classification/ Common/ Proprietary)
5. LEGALLY MARKETING DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
6. DESCRIPTION OF THE DEVICE
7. INTENDED USE OF THE DEVICE
8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

1. SUBMITTER'S NAME

ADRI
232 Main Street – Suite 11A
Park Forest, IL 60466

Phone: (708)747-3717
Fax: (708)747-3657

2. U.S. REGULATORY CONTACT PERSON FOR ADRI

George H. Scherr, Ph.D.
ADRI
P.O. Box 134
Park Forest, IL 60466

Phone: (708)747-3717
Fax: (708)747-3657

510(k) Summary

3. DATE THAT 510(k) SUMMARY WAS PREPARED

April 25, 2004

4. NAME OF THE MEDICAL DEVICE

Classification name	Dressing, wound and burn, (Surgery, 79 MGP)
Common / usual name	Topical Wound Dressing Silver Alginate Foam Dressing
Proprietary names	Trade Names: SilverSite™ or Calgitrol™

5. LEGALLY MARKETING DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

1. CALGITROL™ Ag Silver Alginate Foam Dressing (K011618)
2. ARGLAES-AB™ Antimicrobial Barrier Film Dressing (K970566)
3. ARGLAES-AB™ Antimicrobial Barrier Film Dressing (K990810)

6. DESCRIPTION OF THE DEVICE

The device is a silver ion-containing dressing in which the silver ion is in the form of a molecule of silver alginate. The silver alginate is interspersed in a matrix of calcium alginate and therefore all of the silver in the device is in the ionic state. The silver alginate in its composition prior to layering on a suitable backing is stirred in order to introduce a foam into the silver alginate composition, which foam will materially assist in absorbing exudates from an exuding wound.

The foam composition of the silver alginate gel as composed above has the advantage of absorbing a considerable amount of exudates where such wounds may be treated with this dressing. The layering of the composition as described above is performed on a polyester or polyurethane backing which absorbs excess exudate.

7. INTENDED USE OF THE DEVICE

SilverSite Catheter Dressing containing a slow release anti-microbial silver is intended for use as a hydrophilic wound dressing that is used to absorb exudates and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices. It may be placed under and around external catheter tubing, and held in place on the wound an/or access device by a transparent gas permeable film barrier dressing, or other protective/retention covering; or it may be used as a stand alone device without a secondary cover.

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

The predicate devices are:

1. 510(k) K011618
Calgitrol Ag Silver Alginate Foam
2. 510(k) K970566
ARGLAES-AB Antimicrobial Barrier Film Dressing
3. 510(k) K990810
ARGLAES-AB Antimicrobial Barrier Film Dressing

The device set forth in the instant application is prepared exactly of the same composition as approved in our 510(k) application K011618.

The predicate devices of 510(k) ARGLAES AB (K970566) and 510(k) ARGLAES AB (K990810) provide the same or similar functions, characteristics, and accessories as described herein for the instant device.

Although there are some structural differences between the predicate devices and the instant application device, these differences are minor and raise no new questions of safety or effectiveness.

9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

Studies including Cytotoxicity, Sensitization, Irritation or Cutaneous Reactivity Testing, Microbial Growth Suppression, Microbial Sterility Testing, Analysis for Bacterial Contamination, and Antimicrobial Properties have demonstrated and supported safety and efficacy criteria for this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2004

George H. Scherr, Ph.D
ADRI
P.O. Box 134
Park Forest, Illinois 60466

Re: K041268
Trade/Device Name: CALGITROL™ Ag Silver Alginate Foam and Gel Foam Dressings
with or without Maltodextrin
Regulatory Class: Unclassified
Product Code: MGQ, FRO
Dated: August 23, 2004
Received: August 24, 2004

Dear Dr. Scherr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

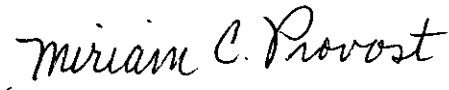
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for 

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K041268

Indications for Use

510(k) Number (if known): K041268

Device Name: CALGITROL™ Ag Silver Alginate Foam and Gel Foam Dressings with or without Maltodextrin

Indications For Use:

Professional Indications (Prescription Use):

Pressure ulcers, Stages I-IV
Dermal lesions (or secreting skin injuries)
Venous ulcers, Stasis ulcers
Intended to protect vascular access sites,
intramuscular sites, and surgical incisions
1st and 2nd degree burns
Donor sites

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K041268

EXHIBIT Q